

K962495

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**510(k) Summary**  
**INDEFLATOR PLUS 30™ Inflation Device**  
**and**  
**PLUS 30 PRIORITY PACK™**

**Device Name:** INDEFLATOR PLUS 30™ Inflation Device  
PLUS 30 PRIORITY PACK™

**Devices to which Equivalence is Claimed:** ACS INDEFLATOR PLUS 20™ (K872981, October 20, 1987) and the ACS 20/30 INDEFLATOR™ (K961471, May 8, 1996).

**Indication for Use:** The INDEFLATOR PLUS 30™ Inflation Device is recommended for use during vascular procedures in conjunction with interventional devices such as balloon catheters to create and monitor pressure in the balloon catheter.

The PLUS 30 PRIORITY PACK™:

INDEFLATOR PLUS 30™ Inflation Device- See description above.

PLUS 30 PRIORITY PACK™ Accessory Kit- The Accessory Kit is recommended for use during vascular procedures in conjunction with interventional and/or diagnostic devices (e.g., balloon dilatation catheters, arterectomy devices, stent delivery systems, intravascular ultrasound devices.)

**Device Description:** INDEFLATOR PLUS 30™ Inflation Device is a manually operated device used to pressurize and depressurize balloon catheters. Pressure can be monitored via a pressure gauge.

The PLUS 30 PRIORITY PACK™ is comprised of the INDEFLATOR PLUS 30™ inflation device packaged with accessories used during vascular procedures in conjunction with interventional or diagnostic devices. These accessories include a torque device, a guide wire introducer and a rotating hemostatic valve.

**Summary of Substantial Equivalence:** The indications, methods and conditions of use, packaging process and location, sterilization process and location are similar to those of the currently marketed ACS INDEFLATOR PLUS 20™ Inflation Device and the ACS 20/30 INDEFLATOR™. The predicate ACS INDEFLATOR PLUS 20™ and the ACS 20/30 INDEFLATOR™, both mechanical inflation devices, are intended to pressurize and depressurize balloon catheters while allowing pressure monitoring via a pressure gauge. The PLUS 30 PRIORITY PACK™ includes accessories that have been previously cleared and the INDEFLATOR PLUS 30™ Inflation device, which is similar to the ACS INDEFLATOR PLUS 20™ Inflation device.

The INDEFLATOR PLUS 30™ Inflation Device and the PLUS 30 PRIORITY PACK™ are similar in design and indicated use to the predicate devices.

**Conclusion:** The INDEFLATOR PLUS 30™ Inflation Device and PLUS 30 PRIORITY PACK™ are substantially equivalent to the currently marketed ACS INDEFLATOR PLUS 20™ Inflation Device and the INDEFLATOR PLUS 30™ mechanical inflation devices.